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M-I-10-6

June 17, 2010

TO: All Regional Food and Drug Directors

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Questions And Answers Received From The Field; Regional Milk Seminars; And FDA Training Courses Held During FY 2009 And The First Quarter of FY 2010

Following are questions and answers received from the field; Regional Milk Seminars (Southeast and Northeast) and FDA training courses (Advanced Milk Processing-Reynoldsburg, OH and Special Problems in Milk Protection-Black Mountain, NC) held during FY 2009; and the Regional Milk Seminar (Central) held during the first quarter of FY 2010.

In accordance with procedures established through the National Conference on Interstate Milk Shipments (NCIMS), if an answer to these questions results in a new understanding of a long-standing situation or installation, and the condition as it exists does not present an immediate public health hazard, reasonable judgment should be exercised and adequate time provided for modification and correction.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers and State Milk Sanitation Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and also will be available on the FDA Web Site at http://www.fda.gov at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to robert.hennes@fda.hhs.gov.

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QUESTIONS AND ANSWERS RECEIVED FROM THE FIELD;

REGIONAL MILK SEMINARS HELD DURING FY 2009-

SE REGION-PENSACOLA BEACH, FL
(OCTOBER 6-9, 2008)

AND

NE REGION-SYRACUSE, NY
(SEPTEMBER 22-24, 2009);

FDA TRAINING COURSES HELD DURING FY 2009-

ADVANCED MILK PROCESSING-REYNOLDSBURG, OH
(JULY 20-24, 2009)

AND

SPECIAL PROBLEMS IN MILK PROTECTION-BLACK MOUNTAIN, NC
(AUGUST 24-28, 2009);

AND THE

REGIONAL MILK SEMINAR HELD DURING THE FIRST QUARTER OF FY 2010-

CENTRAL REGION-HARRISBURG, PA
(NOVEMBER 17-19, 2009)

1. **PMO-Section 1**

A milk plant is utilizing Malted Milk Flavoring Powder in Grade "A" milk to make a Malted Milk Flavored Milk. The primary ingredients of the Malted Milk Flavoring Powder are wheat flour and malt barley, but the product also contains approximately 22% whole milk. Is this Malted Milk Flavoring Powder considered a "powdered dairy blend" within the definition of "Milk Products" of the PMO?

No. Malted milk flavoring powder is considered a flavoring and while it does contain a dairy ingredient, in final form, malted milk flavoring powder is not considered a Grade "A" "powdered dairy blend" as defined in the PMO. It has traditionally been an acceptable flavoring for Grade "A" milk and milk products.

While it is desirable that the milk used to make Malted Milk Flavoring Powder be "Grade "A"", the facility in which the liquid mash and whole milk are blended, condensed and dried is not required to be permitted or regulated under the PMO or to come from an IMS listed source.

According to FDA CPG 7106.01 (copy provided below), to be malted milk, it appears that whole milk needs to be blended in liquid form with "the liquid separated from a mash of ground barley malt and wheat flour, with or without the addition of sodium chloride, sodium bicarbonate and potassium bicarbonate, in such a manner as to secure the full enzymatic action of the malt extract, and by removing water. The resulting product contains not less than 7.5 percent of butterfat and not more than 3.5 percent of moisture."

Sec. 527.500 Malted Milk (CPG 7106.01)

BACKGROUND:

No standard of identity has been established for malted milk. A definition for malted milk was published in Food Inspection Decision (F.I.D.) 170, issued March 31, 1917 and the same definition was included in S.R.A., F.D. No. 2, Revision 5, issued in November 1936. This definition was adopted as a guide in enforcing the Food and Drugs Act of 1906:

<u>Malted Milk</u>

The product made by combining whole milk with the liquid separated from a mash of ground barley malt and wheat flour, with or without the addition of sodium chloride, sodium bicarbonate and potassium bicarbonate, in such a manner as to secure the full enzymatic action of the malt extract, and by removing water. The resulting product contains not less than 7.5 percent of butterfat and not more than 3.5 percent of moisture.

After enactment of the Federal Food, Drug, and Cosmetic Act of 1938, malted milk was among the foods exempted from label declaration of ingredients requirement for labeling of non-standardized foods. The exemption was based on the expectation that standards would soon be established. However, no standard was established and on September 17, 1959, the exemption was terminated. In lieu of a standard the revised definition that appeared in Service and Regulatory Announcement, F.D. No. 2, Revision 5, November 1936, has been used as a guide.

Trade Correspondence (TC-297) issued May 7, 1940 included the following:

"An investigation which we made some years ago showed that malted milk drinks as served at soda fountains normally contain at least 0.5 ounces of malted milk in 10 fluid ounces of beverage. We believe that if you retain the

*name 'Chocolate Flavored Malted Milk Drink' for your product, the manufacturing formula should be revised so that the finished beverage will contain at least 0.5 ounces of malted milk in 10 fluid ounces of beverage. ***"*

POLICY:

In the absence of a standard of identity, the definition published in S.R.A., F.D. No. 2, Rev. 5, November 1936, will serve as a compliance guide for the identity of malted milk.

Issued: 10/1/80
Revised: 8/96

2. **PMO-Section 1, Definition X. Milk Products**

Grade "A" Determination Requested from FDA's Imports Personnel:

Upon review of the Fromagerie Marie Kade (Canada), Ayran Yogurt Drink labels, the product is labeled as containing 95% moisture and 1% milkfat. Therefore, it has only 5% total solids. Water is listed first on the ingredients statement, which indicates that the product contains less than 50% Labane ("Labane" is cited in the ingredients statement; however, the name of the milk product as indicated on the principle display panel is "Yogurt Drink", not "Labane"). Further information is needed, including which bacterial cultures are being used, so that CFSAN's Office of Nutritional Labeling and Dietary Supplements (ONLDS) can determine if "Fromagerie Marie Kade's "Yogurt Drink"" is "yogurt" or a "Labane" product and whether the words would be considered synonyms as to labeling. **(NOTE:** This is a labeling issue that is not addressed in this M-I but needs to be handled by ONLDS.)

Ingredients: Water, Labane (Pasteurized Milk, Bacterial Culture), Salt.

The Nutrition Facts panel indicates a protein content of 1.25 g per cup/8 fl. oz., which equates to approximately 0.5% protein.

Grade "A" Determination:

- *Utilizing Definition X. Milk Products from the 2007 PMO and the criteria that FDA has used in the past for making such Grade "A" determinations for milk products (containing at least 50% milk or milk products to be considered Grade "A"), this Ayran Yogurt Drink would not be considered Grade "A".*

- *Utilizing the new Definition X. Milk Products contained in the 2009 PMO, which states that for a milk product to be considered Grade "A" it must have a minimum of 2.0% milk protein and a minimum 65% by weight of*

*milk, milk product or a combination of milk products, this Ayran Yogurt Drink would also not be considered Grade "A" based on this new definition. (**NOTE:** FDA will utilize the definition for Milk Products incorporated into the 2009 PMO for making such Grade "A" determinations from this point forward.)*

3. **PMO-Section 1, Definition X. Milk Products**

Would pasteurized liquid whey packaged for individual consumer sales from an IMS Listed cheese plant be considered Grade "A" under Definition W-Milk Products of the PMO?

Yes.

4. **PMO-Section 1, Definition X. Milk Products**

Would buttermilk collected from Grade "A" milk and cream from an IMS Listed milk plant that is packaged for individual consumer sales or bulk sales that comes directly off of a continuous churn, which meets the construction requirements of Item 11p-Construction and Repair of Containers and Equipment of the PMO, and which is not cultured, be considered Grade "A" as meeting Definition W-Milk Products of the PMO?

Yes.

5. **PMO-Section 1, Definition X. Milk Products; and Appendix L**

a) Would eggnog that contains alcohol, i.e., Brandy/Rum/Whiskey, which is added above an amount used strictly as a flavoring to eggnog, be considered a Grade "A" Milk Product under Definition X-Milk Products of the PMO?

NOTE: Generally the addition of less than 0.5% alcohol is used as a flavoring when added to eggnog.

No.

b) May this product be labeled as "eggnog" with the alcohol addition?

The following answer was provided by CFSAN's Office of Nutrition, Labeling and Dietary Supplements (ONLDS):

FDA would not normally object to a product being called eggnog if it meets the FDA standard of identity for eggnog contained in 21 CFR 131.170. However, if the product contains a quantity of alcohol over that which would just flavor the product, it is not the standardized food and should be named

with a sufficiently descriptive term that adequately distinguishes it from the standardized food.

c) What Agency would regulate such a product?

The Alcohol and Tobacco Tax and Trade Bureau (TTB) is responsible for labeling of "spirit beverages", which are beverages that contain 0.5% or greater alcohol. FDA is responsible for the safety of all alcoholic beverages; however, under the terms of a Memorandum of Understanding (MOU), enforcement is the responsibility of TTB.

d) Would eggnog that contains alcohol, i.e., Brandy/Rum/Whiskey, added solely as a flavoring to eggnog (generally considered less than 0.5%) be considered a Grade “A” Milk Product under the definition of “Milk Products” within the PMO?

Yes. This would be considered flavored eggnog.

6. **PMO-Sections 1 and 4**

A milk plant receives raw goat’s milk from manufacturing grade goat farms. The raw goat’s milk is currently used in processing cheese and other manufactured grade goat milk products. May this milk plant use this manufacturing grade goat milk to make "Non-Grade “A” Goat’s Milk Yogurt"?

No. Yogurt is a PMO defined milk product and the State is required to adopt the PMO or have equivalent State laws and regulations. Therefore, only Grade “A” milk can be used in its production and it would NOT be acceptable to make goat’s milk yogurt from manufacturing grade goat’s milk.

7. **PMO-Sections 1 and 7, Item 16p**

Camel’s milk is between "normal" Holstein and Jersey cow's milk on a fat and solids basis. What are the appropriate times and temperatures for the legal pasteurization of camel’s milk?

There is a very similar compositional makeup of camel’s milk in regard to bovine milk and as long as the PMO’s Standard Plate Count (SPC) standard for raw camel’s milk is the same as for bovine milk, the use of the same legal pasteurization times and temperatures as that used for bovine milk would also be appropriate for camel’s milk.

8. **PMO-Sections 1 and 4; and Appendix L**

The finished Grade “A” milk product in question is fat-free whipping cream packaged in an aerosol can. The fat-free whipping cream contains vanilla

flavoring that consists of several ingredients of which one (1) is caramel color (0.176%). The vanilla flavoring is used at 0.05% in the 20% fat-free whipping cream and the finished product contains 0.000088% (0.88ppm) caramel color. In this case, would the caramel color be considered an incidental additive; therefore, not being required to be declared on the label or does color, at any level, require to be declared on the label for this milk product?

The following answer was provided by CFSAN's ONLDS:

Under 21 CFR 101.100(a)(3), incidental additives are described as being present at insignificant levels and not having any technical or functional effect in the finished food. Incidental additives are exempt from ingredient labeling requirements.

According to the description above, if the caramel color, which is added to color the vanilla flavoring and does not color the finished food, then it does not have any technical or functional effect in the finished milk product (fat-free whipping cream). In addition, FDA believes that the amount of caramel color in the finished product (0.88ppm) is present at an "insignificant level" in this particular finished food. Because the caramel color is present at an insignificant level and does not have a technical or functional effect in the finished food, then it may be considered an "incidental additive". The caramel color; therefore, is not required to be declared in the ingredient statement.

9. **PMO-Sections 1 and 4; and Appendix L**

Titanium dioxide is being added to Grade "A" fat-free half and half to improve the appearance of the milk product. If the milk plant can demonstrate that the added color is needed to whiten "fat-free half and half", so that it is as white as regular half and half, but does not enhance the product's color, then would this addition of titanium dioxide be allowable under 21 CFR 130.10?

The following answer was provided by CFSAN's ONLDS:

21 CFR 130.10(c)-(d) details allowable deviations from the food standards of identity. Under 21 CFR 130.10(c), criteria are given for substitute foods to ensure that these foods possess performance characteristics similar to the standardized food.

Accordingly, if titanium dioxide is to be used as a color additive to improve the appearance of "fat-free half and half", it may not enhance or change the color of the "fat-free half and half" version beyond that of the regular half and half product. In other words, the "fat-free half and half" version cannot appear to be better than the regular product, for which a food standard of identity exists.

In addition, 21 CFR 73.575(c) lists any restrictions for using titanium dioxide as a color additive. 21 CFR 73.575(c)(1) states that the quantity of titanium dioxide, if used as a color additive, "may not exceed 1 percent by weight of the food".

As per usual, titanium dioxide must be listed in the ingredient declaration [21 CFR 73.575(c)].

10. **PMO-Sections 1 and 4; and Appendix L**

Currently the CFR Standard of Identity for yogurt is stayed in part and allows for other safe sources of dairy solids; however, that is for cow's milk yogurt.

a) May ultra-filtered (UF) goat's milk be used as an ingredient in goat's milk yogurt?

The following answers were provided by CFSAN's ONLDS:

FDA published a proposed rule recently (74 FR 2443, January 15, 2009) proposing to amend the standard of identity for yogurt and revoke the standards of identity for lowfat yogurt and nonfat yogurt. In that proposal, FDA addressed all of the stayed provisions in the current yogurt standards. In proposed section 21 CFR 131.200(c), we proposed to permit any safe and suitable milk-derived ingredient as an optional dairy ingredient for the purpose of increasing the nonfat solids content of yogurt, provided that the ratio of protein to total nonfat solids of yogurt and the protein efficiency ratio (PER) of all protein present is not decreased as a result of the addition of the optional milk-derived ingredient. Please refer to the discussion on page 2450 of 74 FR 2443, January 15, 2009, for additional information. In addition, the proposal noted the Agency's intention to consider the exercise of its enforcement discretion on a case-by-case basis when yogurt products are in compliance with the proposed provisions (refer to page 2455).

Consistent with these proposed provisions, yogurt may be manufactured using UF milk as an optional ingredient (not as a basic ingredient) for the purpose of increasing the nonfat solids content of the food.

b) Would this FDA proposed rule also apply to goat's milk yogurt?

Yes. Although this proposal relates to "yogurt" that is made with cow's milk, ONLDS believes that FDA would apply the same approach to goat's milk yogurt manufactured using UF goat's milk as an optional ingredient.

c) Is there any time frame of when the proposed rule will become a final rule?

FDA will consider comments received in determining further actions; however, at this time, FDA does not have a specific time frame to go to final rule.

11. **PMO-Sections 1 and 4; and Appendix L**

May “Reb-A”, brand name “Stevia”, or other sugar substitutes such as “Splenda”, which are considered non-nutritive extract sweetener, be used as an alternative substance for sugar in producing Grade “A” flavored milk or milk products such as a "lower sugar chocolate milk"?

The following answer was provided by CFSAN’s ONLDS:

The standard of identity for “Milk” allows for nutritive sweeteners to be added to flavors that may be added to milk. Therefore, a non-nutritive sweetener like “Splenda” or the “Stevia” extract sweetener cannot be added to the food, "___ milk". The blank to be filled in by the flavor. However, under the provisions of 21 CFR 130.10, which is the regulation governing a modified standardized food that uses a nutritive content claim, a non-nutritive sweetener can be added to a food such as a "lower sugar chocolate milk," as long as the sweetener is approved or GRAS and the product complies with the nutrient content claim.

12. **PMO-Section 4**

In order to use the statement "Excellent Source of Calcium" or "Good Source of Calcium" on the label of a milk product such as whole milk or any of the reduced fat milks, what percent or how much calcium is required to make such a label claim?

The following answer was provided by CFSAN’s ONLDS:

The requirements for “good source” and “excellent source” are found in 21 CFR 101.54. For a product to bear a “Good Source” claim, it has to contain at least 10% of the daily reference value (DRV) or daily reference intake (DRI) per serving of the nutrient that is the subject of the claim. A product is eligible to bear an “Excellent Source” claim if it contains at least 20% of the DRV or DRI per serving. For calcium, the food must contain at least 100 mg to bear a “Good Source” claim and at least 200 mg to contain an “Excellent Source” claim. The DRI for calcium is 1000 mg.

13. **PMO-Section 4**

a) A Grade “A” 1% milk product with the addition of Lactobacillus acidophilus and Bifodobacterium lactis (bifidus) cultures is being labeled as “1% MILKFAT LOWFAT MILK VITAMINS A&D” and also with the terms "Body + Boost" and "Probiotics". Would this be acceptable?

The following answers were provided by CFSAN's ONLDS:

- *With regard to the statement of identity for this milk product:*

  "1% MILKFAT LOWFAT MILK VITAMINS A&D" does not appear to be an appropriate statement of identity for this food. "Low fat milk" is a food subject to the requirements of 21 CFR sub-part 130.10. We see no provision under 21 CFR 130.10 that provides for the addition of Lactobacillus acidophilus and Bifodobacterium lactis (bifidus) cultures to the food named by the nutrient content claim "low fat" and the standardized food name " milk". We note that acidophilus and bifidus cultures are permitted in the standardized food cultured milk (21 CFR 131.112). If this product meets the standard of identity for cultured milk it should be identified as such.

- *With regard to the use of the term "BODY + BOOST":*

  FDA does not have any reason to object to the use of the fanciful terms "BODY + BOOST" and are not aware of any objections to the use of these terms on a food label to date.

b) As a follow-up question, has FDA developed a definition for "Probiotics"?

   No.

14. **PMO-Section 4**

What is FDA's guidance on the use of rBST Free labeling for nonfat dry milk (NFDM)? Would it be the same as for fluid milks and milk products?

The following answer was provided by CFSAN's ONLDS:

FDA's guidance would be the same for NFDM and other dried milks and milk products as for fluid milks and milk products. Accompanying the statement "from cows not treated with rbST", the statement that "No significant difference has been shown between milk derived from rbST-treated and non-rbST treated cow" would be required.

15. **PMO-Section 4**

Whey powder and nonfat dry milk (NFDM) are being added to a Grade "A" milk or milk product and in the ingredient statement on the label they wish to state "Milk Solids" for these two (2) dairy ingredients that are being added. Would this be acceptable?

The following answer was provided by CFSAN's ONLDS:

No. The use of the term "milk solids" is not an appropriate common or usual name for declaring these ingredients on any milk or milk product. This milk or milk product must declare the ingredients using the common or usual names of "whey powder" and "nonfat dry milk" or as provided in 21 CFR 101.4(b)(2)(ii) as "whey" and "nonfat milk" in the ingredient statement on the label.

16. **PMO-Sections 4 and 7, Item 16p(E); and Methods of Making Sanitation Ratings of Milk Shippers (MMSR)-Section D**

a) For Grade "A" ultra-pasteurized labeled milk and milk products, which are legally pasteurized in an approved and quarterly tested HTST system prior to entering the ultra-pasteurization (UP) system, is the State Regulatory Agency responsible for conducting the testing of the thermometers and the determination of the holding tube length and diameter for the UP system to assure that the milk or milk product UP label designation is appropriate or can they have an outside company come in and test the thermometers on the UP system?

The State Regulatory Agency is required to test the indicating and recording thermometers for accuracy and the length and diameter of the holding tube shall be determined to evaluate if the UP system meets the manufacturer's calculated holding time. These tests are used to verify that the UP labeling designation is appropriate.

We would not object to this required testing being conducted by an outside company that is acceptable to the State Regulatory Agency. This testing shall be conducted under the direction of the State Regulatory Agency and shall be physically supervised by personnel of the State Regulatory Agency.

b) At what frequency is this testing required?

This required testing should be conducted on a routine basis as determined by the State Regulatory Agency. It is recommended that this required testing be conducted at least once every twelve (12) months.

c) If the testing results or the UP system processing records do not verify that the UP system will assure that the milk and milk products have met the UP temperature and time requirements of 280ºF or higher for 2 seconds or longer for a milk or milk product to be labeled "Ultra-Pasteurized", what actions should a State Rating Officer or FDA Regional Milk Specialist take?

If either the testing results or the UP system processing records do not verify that the UP labeling requirements are being met, than this would be considered a labeling violation of the CFR and the PMO and would be debited under PART III-Individual Shipper Rating, Item 3-All Milk and Milk

Products Properly Labeled on FORM FDA 2359j-Report of the Milk Sanitation Rating, Section B-Report of Enforcement Methods (Page 2) for each of the milk or milk products that are affected.

17. **PMO-Sections 5, 6 and 7, Item 16p(E); and MMSR-Sections B, C and D**

A State has asked if they can keep only electronic records and ledgers that are required under the PMO and other related NCIMS documents and paper copies will not being generated or filed. They stated that there may still be some hard copy records required for such things as water samples, product samples, pasteurization equipment checks; however, all farm and plant inspection reports will be conducted on a computer utilizing electronic signatures. Is this permissible under the PMO and other related NCIMS documents?

Yes. It would not be considered a problem with this approach to any of the State Regulatory Agency's required PMO records and ledgers as long as all of the requirements of the PMO are fully met (ledgers when required, retention times respected, files kept together, or can be easily grouped, by permit holder, etc.). The nature of some records and ledgers may still dictate hard copies be kept, such as laboratory results from product and water results, if the laboratory does not have the means to provide them electronically.

Remember, if the data is lost, it would be considered the same as if paper records were not available.

As long as the records and ledgers are readily available in a format that can be easily read and the State Regulatory, State Rating Officer(s) and FDA Regional Milk Specialist(s) can accomplish everything that is required under the IMS program, it should not make a difference whether the records and ledgers are written and recorded with a pen or a keyboard or if you can read them from a piece of paper or off of a screen.

Also, the State should check with their legal counsel to make sure that they have the authority to take enforcement action based on an electronic record.

18. **PMO-Section 6**

A milk plant produces heat-treated cream, which will be further processed as pasteurized cream in this milk plant. This milk plant does not ship out any heat-treated cream. Does Section 6-The Examination of Milk and Milk Products of the PMO require the sampling and testing of this heat-treated cream at this milk plant?

No.

19. **PMO-Section 6; and MMSR-Sections F and H**

a) What Section 6 testing is required for Grade “A” bulk buttermilk obtained directly from the butter churn, which is not cultured, that is shipped from Milk Plant A to Milk Plant B?

Grade "A" buttermilk is required to be made from pasteurized Grade "A" cream and must be produced in a milk/cheese plant that complies with Item 1p-15p and 17p, 20p, 21p and 22p of the PMO as cited on page 28 of the 2009 PMO. The bulk shipped buttermilk from Milk Plant A, which is obtained directly from the butter churn and which is not cultured, would be considered a Grade "A" pasteurized milk product. Therefore, samples need to be collected at the shipping plant (Plant A) to comply with Section 6 of the PMO and be tested for temperature, SPC (not to exceed 20,000/mL), and coliform (not to exceed 100/mL). Because there are not any approved laboratory methods for phosphatase or antibiotics for buttermilk these tests would not be required.

b) Which Product Code would this Grade “A” bulk shipped pasteurized buttermilk, which has not been cultured, be classified under for the shipping milk plant?

Product Code #2-Pasteurized Milk, Reduced Fat, Lowfat, Skim.

c) The receiving milk plant (Milk Plant B) is repasteurizing the Grade “A” bulk buttermilk and then drying the buttermilk. Plant B is listed for Product Code #17-Buttermilk (Condensed or Dry). Are there any Section 6 testing requirements for the incoming bulk pasteurized buttermilk at the receiving milk plant (Milk Plant B)?

No.

20. **PMO-Sections 6 and 7, Item 9r; and Appendix B, Section I**

a) Is a farm holding/cooling bulk milk tank required to have a permanently installed and operational agitator?

No, the PMO does not specifically cite such a requirement; however, the proper agitation of the farm bulk milk tank is required for the collection of a “universal sample”.

b) If not, what are the requirements for agitation?

Appropriate, sanitary means must be available to provide the required agitation, based on the size and shape of the farm bulk milk tank, before the bulk farm bulk milk tank and pickup the milk for transportation to a receiving

*facility. If appropriate agitation cannot be provided at the farm, then the bulk milk hauler/sampler cannot collect a representative universal sample and the bulk milk hauler/sampler should not pickup the milk. If a sample is collected from this non-agitated or insufficiently agitated farm bulk milk tank then the integrity of the samples collected from this farm bulk milk tank are in question and the bulk milk hauler/sampler should be asked what information was used to determine proper agitation. It is the responsibility of the bulk milk hauler/sampler to agitate the milk a sufficient time to obtain a homogeneous product prior to sampling and the subsequent picking up of the milk. They need to follow the State Regulatory Agency's and the manufacturer's guidelines for proper agitation. (**NOTE**: 3-A Standards 13-09 – For tanks which have been modified, the agitation time indicated on the information plate may not be appropriate.) If acceptable samples cannot be collected because of insufficient agitation, the ultimate responsibility for the correction of this PMO violation is the dairy producer's. The bottom line is for the Regulatory Agency to require the dairy producer to resolve this PMO violation so that representative universal samples may be collected. For additional information refer to Standard Methods for the Examination of Dairy Products (SMEDP), Chapter 3, 3.036-agitators and 3.042-agitation and 3-A Standards 13-09.*

NOTE: *If an agitator(s) is installed on a farm bulk milk tank and the agitator(s) is not properly constructed or is not in good repair this would be considered a violation of Item 9r-Utensils and Equipment-Construction of the PMO.*

21. **PMO-Section 6; and Appendix N, Section I**

May a milk plant use a sampling device, similar to a "core" sampling design, to obtain a representative sample from milk tank trucks, without agitation, for Section 6-The Examination of Milk and Milk Products and Appendix N-Drug Residue Testing and Farm Surveillance sampling requirements of the PMO?

No. FDA's Laboratory Proficiency and Evaluation Team (LPET) states that this sampling device has not been evaluated by them to meet the representative sampling requirements for a sample collected from a milk tank truck, with or without agitation, for Section 6 or Appendix N sampling purposes. Therefore, this sampling device would not be acceptable under the PMO for the collection of samples for Section 6 or Appendix N milk tank truck sampling requirements, with or without the proper agitation of the milk tank truck.

22. **PMO-Section 6; and Appendix N, Section 5**

Sheep have a short lactation period and give a small amount of milk. Sheep producer/processors normally freeze a day's production until they have

accumulated enough milk to produce a batch of milk, milk product or cheese. The milk is thawed slowly in a refrigerator. Then the raw milk is tested for antibiotics prior to beginning processing. May frozen samples of raw sheep's milk be tested by the Charm SL procedure for official regulatory purposes under Section 6-The Examination of Milk and Milk Products and Appendix N-Drug Residue Testing and Farm Surveillance of the PMO?

No. The Charm SL drug test kit was not validated by CVM for use with frozen raw sheep milk. The raw sheep milk must be tested prior to freezing.

23. **PMO-Section 7, Preamble and Item 16p, Preamble**

Does a microfiltration process/system that is being used to remove and/or deactivate bacteria from raw milk as provided for in the Preamble to Section 7-Standards for Grade "A" milk and Milk Products of the PMO fall under the guidelines found under Item 16p.-Pasteurization and Aseptic Processing, Administrative Procedures #3.b, of the PMO?

Yes. The microfiltration process/system being used to remove and/or deactivate microorganisms from raw milk for pasteurization would have to be installed and operated in accordance with the provisions of Item 16p, Administrative Procedures #3 of the PMO.

24. **PMO-Section 7, Item 1r**

A quarter milking unit, is generally a two (2) gallon collection container, which is used to intercept milk from an identified quarter of the udder through an isolated inflation line in order to divert milk from a quarter afflicted by high somatic cell count, injury, mastitis, hemorrhage, etc., during milking. According to the literature, it is not to be used for the milking of antibiotic-treated cows.

Non-treated lactating dairy animals are being milked with the swing line directly connected to the farm bulk milk tank. May a quarter milking unit be used to milk one (1) or more quarters of these non-treated lactating dairy animals?

No. Using a quarter milking unit during milking time, as currently designed (common teat cup, safety valve design, vacuum pulled from milk line, etc.), would constitute a violation of Item 1r-Abnormal Milk of the PMO. The quarter milking unit shall be cleaned after each use and if found dirty, improperly stored or constructed when stored in either the milkhouse or milking area it would be considered a violation of Item 1r.

25. **PMO-Section 7, Item 3r**

If the surface of the jetter cups with which the inflations come in contact with during CIP cleaning and storage during non-milking times are observed to be dirty in the milking parlor during a State rating or FDA check rating, is this considered a violation of the PMO and where would it be debited?

If a significant number of the jetter cups (generally considered 50% or greater) are dirty it would be considered a violation of Item 3r-Milking Barn, Stable or Parlor – Cleanliness.

26. **PMO-Section 7, Items 3r and 19r**

a) Is a wooden feed cart(s) that is used to store or distribute feed, acceptable for use and its storage, with or without feed in it, in milking barns?

Yes.

b) If the wooden feed cart(s) is in poor repair would this be considered a violation of the PMO?

Only if it will attract birds, rodents and insects and is not covered.

c) Are there situations when a wooden feed cart(s) or any feed storage container or distribution system would be considered a violation of the PMO?

Yes.

Item 3r-Milking Barn, Stable or Parlor: If the feed is stored in such a manner that it increases the dust content of the air or the cart interferes with the cleaning of the floor.

Item 19r-Insect and Rodent Control: If the feed is stored in the milking portion of the milking barn in such a manner that it will attract birds, rodents or insects and the wooden cart, other storage containers or the distribution system is not covered. Remember that within this Item of the PMO it allows for feed dollies, carts, fully automated feeding systems, or other feed containers to be exempt from the use of covers, provided they do not attract birds, insects, or rodents.

27. **PMO-Section 7, Items 5r-Floors**

If the cover plate for a floor drain in a milkhouse is misaligned or missing entirely, would this be considered a violation of Item 5r-Floors of the PMO?

No.

28. **PMO-Section 7, Items 5r-Lighting**

On non-electric dairy farms (Amish), is a lantern(s) required to be located in the milkhouse at all times or can they have a hook(s) located to provide adequate light in the milkhouse when they bring in a lantern(s) and place it on the hook(s)?

A designated lantern(s), which is located in the milkhouse at all time, is required.

29. **PMO-Section 7, Items 8r**

On non-electric dairy farms (Amish), air is being injected directly into the well for the pressurization of their water system.

a) Is the air supply required to be free of oil, dust rust, excessive moisture, extraneous materials and odors?

Yes.

b) Does this mean that they are required to have a properly installed and maintained final filter in the air line as close as possible to the point of application?

Yes.

c) If a) or b) above is not being complied with, would either one of these or both of these be considered a violation of Item 8r-Water Supply or Item 14r-Protection from Contamination of the PMO?

Both would be considered a violation of Item 8r (2 point debit).

30. **PMO-Section 7, Item 8r**

Does the water outlet line from a plate cooler on a dairy farm that pipes this water to a storage vessel or to a stock watering tank required to be screened?

No.

31. **PMO-Section 7, Item 9r**

Are rubber or plastic slip joints acceptable to be used on milk or CIP pipelines to connect and hold in place two pieces of stainless steel piping?

No.

32. **PMO-Section 7, Items 9r and 14r**

Is it considered a violation of Item 9r-Utensils and Equipment – Construction of the PMO if a farm bulk milk tank that utilizes an outside measuring tube has the measuring tube connected to the farm bulk milk tank outlet valve when the tank has milk in it, the outlet valve is closed, and there is not any milk in the measuring tube?

Yes, the measuring tube must be constructed so that after milk enters the measuring tube, it can only be discarded. If the measuring tube is not constructed in this manner, the measuring tube must be disconnected from the farm bulk milk tank when milk is stored in the tank. If it is observed that a measuring tube is not designed to ensure that milk collected in the measuring tube is discarded and the measuring tube is not disconnected when there is milk in the tank that would be considered a violation of Item 9r-Utensils and Equipment – Constructed.

Also, if the measuring tube is connected to the top of the bulk milk tank, with milk in the tank, the opening to the measuring tube when disconnected shall also be properly protected. If it is not properly protected, it would be considered a violation of Item 14r-Protection from Contamination.

33. **PMO-Section 7, Items 10r and 11r**

a) Is the absence of an acceptable sanitizer on a dairy farm still considered a violation of Item 11r-Utensils and Equipment - Sanitization?

Yes.

b) If the answer is yes, then why is it not considered a violation of Item 10r-Utensils and Equipment - Cleaning if a cleaner is not available on the dairy farm?

Equipment cleaning is evaluated and determined through the visual inspection of the equipment. The absence or presence of a cleaner on the dairy farm is not the basis utilized for determining if a piece of equipment is clean or not.

34. **PMO-Section 7, Item 14r**

If a farm bulk milk tank's agitator(s) is located outside or in an area that does not meet milkhouse construction and cleanliness requirements and appropriate shielding is required, is this required shielding required to be transparent?

No, but it must be readily removable for inspection and cleaning.

35. **PMO-Section 7, Item 15r**

FDA's policy on extra label use of drugs in food producing animals is described in FDA's Compliance Policy Guide (CPG) 7125.06, which requires that when a veterinarian extra labels an animal drug that the label must include the identification of the farm or herd for which the medication is being extra labeled. Is this identification of the farm or herd required under Item 15r of the PMO?

No. However, if it is observed that a veterinarian is not identifying the farm or herd on the extra label, then this should be reported to your FDA Regional Milk Specialist.

36. **PMO-Section 7, Item 16r**

On a dairy farm, may one (1) compartment of a two (2) compartment wash vat be used for COP and the other compartment designated for handwashing if the dairy farm also has a separate upright CIP vat.

Yes, as long as the compartment used for handwashing is properly designated for handwashing use only.

37. **PMO-Section 7, Items 18r**

If a dairy farm producer voluntarily installs a farm bulk milk tank temperature-recording device on a farm bulk milk tank that was manufactured prior to January 1, 2000, is the temperature-recording device and the producer required to comply with the requirements of Item 18r-Raw Milk Cooling, Administrative Procedures #3, of the PMO?

No.

38. **PMO-Section 7, Items 18r and 17p; and Appendix N, Section 5**

May a Grade "A" producer ship sheep milk that is frozen to a milk plant?

Yes. It must be stored, handled and transported under sanitary conditions and properly thawed at the processing facility under sanitary conditions so that it does not exceed 45ºF or become otherwise contaminated at anytime.

NOTE: *The sheep milk must be tested for antibiotics (Appendix N) prior to be being frozen. (Refer to question #22.)*

39. **PMO-Section 7, Items 18r; and Appendix H, Section V**

a) A dairy farm has installed an electronic data collection and storage system for their required temperature-recording device on their farm bulk milk tank/silo. The data is stored internally in the control box, which is located in the milkhouse, until it is downloaded to a computer. Once downloaded to the computer, the temperature data is printed once every seven (7) days. The control box located in the milkhouse does not allow for the viewing of the farm bulk milk tank temperatures since the graph was previously printed. A real-time display is available on the control box in the milkhouse for the current temperature conditions inside the tank. Is it a violation to not have the last few days of data available for review, if all the other data printouts are handled correctly?

Acceptable electronic data collection and storage system used on dairy farm bulk milk tanks/silos must have the capability of printing out the data for any period of time that may be needed or requested by the Regulatory Agency, State Rating Officer or FDA Regional Milk Specialist. If the electronic data collection and storage system being utilized does not have that capability, it would be considered in violation of Item 18r-Cooling of Raw Milk of the PMO.

NOTE: *It is the Regulatory Agency's responsibility to determine which means, either off the screen or printed materials, which they will utilize for their review of these required electronic records.*

b) How often must the data be printed out?

There is not an established or required frequency of how often the data must be printed out. Remember, that the electronic data collection and storage system must be capable of printing out the data as cited in the answer to a) above.

c) A dairy farm has installed an electronic data collection and storage system for their required temperature-recording device on their farm bulk milk tank/silo. It is wired directly to a computer that is accessible to the Regulatory Agency, and all temperature data can be viewed visually on the computer screen for current conditions and for any length of history required. Must the electronic data collection and storage system have the ability to print out the data for a hard copy or is the screen viewing of the records on the computer acceptable?

Please refer to the answer provided in a) above. The electronic data collection and storage system must have the capability of printing out the data for any period of time that may be requested by the Regulatory Agency, State Rating Officer or FDA Regional Milk Specialist.

40. **PMO-Section 7, Item 7p**

Is it acceptable to exchange heat between cow water and water from an open, evaporative cooling tower in a plate heat exchanger with cow water on one (1) side and tower water on the other side?

No. Water for use in a milk plant must be from a safe source and be properly protected. One (1) method of protecting the cow water from the open tower water used in a plate heat exchanger as described above is through the use of an intermediate cooling media loop. If such an intermediate cooling media loop is used it must be protected against infiltration and contamination at all times, and must be located between the cow water and the open, evaporative cooling tower water. If a plate or double/triple tube heat exchanger is used to exchange heat between the water from the open tower and the water in the intermediate cooling media loop it must be protected by an isolation system. This isolation system must be constructed, installed and operated in accordance with the criteria outlined in Item 17p-Cooling of Milk and Milk Products of the PMO.

41. **PMO-Section 7, Items 7p and 15p(A)**

May the required fail-safe valve that is used as a component of a valving arrangement designed to prevent water from entering milk and milk products through water piping that is continuously connected to milk or milk product lines or vessels as required in Item 7p-Water Supply of the PMO be of a "turning disk", which is not a butterfly type valve? Turning disk type valves are manually operated and are acceptable only for "low pressure" applications.

No. A manually operated valve is not considered to be "fail-safe". If the turning disk type valve can be mechanically operated, is constructed and inter-wired to be considered fail-safe and is compatible with the pressures within the system, we would not object to its use in this application.

42. **PMO-Section 7, Items 7p and 15p(A)**

a) Is the water that is directly connected to evaporators and used for start-up, shut down or emergencies required to be potable and comply with Item 7p of the PMO?

Yes.

b) Are direct water connections to an evaporator, which are used for start-up or the flow-diversion device (FDD) diversion and are located downstream from the FDD and before the first effect, required to comply with Item 15p(A)-Protection from Contamination, Administrative Procedures #19, of the PMO?

Yes.

43. **PMO-Section 7, Item 7p; and Appendix D, Section V**

Appendix D-Standards for Water Sources, V-Water Reclaimed from Milk and Milk Products and from Heat Exchangers or Compressors in Milk Plants, Category I-Used for Potable Water Purposes, Item 7, of the PMO states that approved chemicals, such as chlorine, with a suitable detention period, may be used to suppress the development of bacterial growth and prevent the development of tastes and odors. Would it be acceptable if a milk plant uses an ultraviolet (UV) light or ozone to suppress bacterial growth for this purpose?

No. The current wording of this Section of the PMO does not allow for the use of UV light or ozone to suppress bacterial growth in water reclaimed from milk and milk products and from heat exchangers or compressors in milk plants.

44. **PMO-Section 7, Item 11p**

Are continuous butter churns, which are used to produce Grade "A" buttermilk, required to be constructed to meet the requirements of Section 7, Item 11p-Construction and Repair of Containers and Equipment, of the PMO?

Yes.

45. **PMO-Section 7, Item 12p**

a) If a significant number of the interior of vents (bleeds) on block-n-bleed valve arrangements are found to be dirty (generally considered 50% or greater) with milk soils on a State rating of FDA check rating, would this be considered a violation of the PMO?

Yes.

b) If so, would it be considered a violation of Item 9p-Milk Plant Cleanliness, Item 12p-Cleaning and Sanitizing of Containers and Equipment (12(a)-Cleaning only or 12(a) and (c)-Cleaning and Sanitizing), or Item 15p-Protection from Contamination?

Item 12p(a) and (c).

46. **PMO-Section 7, Item 12p; and Appendix B, Section IV**

Proposal 252 from the 2009 NCIMS Conference passed with a substitute solution that requested FDA to issue a memorandum clarifying documentation of proper cleaning and sanitization for multiple loads. Below is the wording that was discussed at the 2009 NCIMS Conference and agreed to by the author of the Proposal and FDA. This wording is to be incorporated in an M-I addressing questions and answers. With the issuance of this M-I, FDA considers that it has fulfilled its obligation with the passage of Proposal 252.

Item 12p-Cleaning and Sanitizing of Containers and Equipment and Section IV-Milk Tank Truck Permitting and Inspection, Appendix B. Milk Sampling, Hauling and Transportation, of the PMO require that a cleaning and sanitizing tag shall be affixed to the outlet valve of the milk tank truck or a record shall be made showing the date, time, place and signature or initials of the employee or contract operator doing the work, unless the milk tank truck delivers to only one (1) receiving facility where responsibility for cleaning and sanitizing can be definitely established without tagging. When the milk tank truck is next washed and sanitized, the previous cleaning and sanitizing tag shall be removed and kept on file at the location where the milk tank truck was washed for a period of time of not less than fifteen (15) days as directed by the Regulatory Agency.

If the milk tank truck requires and utilizes a cleaning and sanitizing tag affixed to the outlet valve of the milk tank truck, does the PMO prohibit a milk receiving facility from making and retaining a copy of the cleaning and sanitizing tag from those milk tank trucks that delivered milk to that milk receiving facility and were not cleaned and sanitized at that milk receiving facility?

No, provided the original cleaning and sanitizing tag, after it has been copied, is re-affixed to the outlet valve of the milk tank truck and kept with the milk tank truck until it is removed when the milk tank truck is next washed and sanitized.

47. **PMO-Section 7, Item 12p; and Appendix H, Section IV**

May a twenty-four (24) hour recording device be used in place of a seven (7) day recording chart on raw milk storage tanks/silos that store milk or milk products longer than twenty-four (24) hours in a milk plant and fulfill the requirements of Item 12p-Cleaning and Sanitizing of Containers and Equipment, Administrative Procedures #1, of the PMO?

No. Item 12p of the PMO specifically requires a seven (7) day temperature recording device which complies with the specifications of Section IV-

Thermometer Specifications, Appendix H-Pasteurization Equipment and Procedures for Other Equipment, of the PMO.

48. **PMO-Section 7, Item 15p(B); and Appendix H, Section IX**

A pasteurized water equivalent system process, previously accepted by both the State Regulatory Agency and FDA, utilizes a five (5) micron or less absolute filter in conjunction with a ultraviolet (UV) light system, which now does not meet the new UV light requirements contained within the 2009 PMO, and the water, which is determined to be equivalent to pasteurized water, is used to push pasteurized milk and milk products as required in Item 15p-Protection from Contamination of the PMO. Would this previously accepted pasteurized water equivalent system process, which utilizes a UV light water treatment system, now be required to be brought into compliance with the new UV light requirements as cited in the 2009 PMO?

No, It would not have to be updated at this time to meet the 2009 PMO requirements for UV light because there should have been scientific data presented to the State Regulatory Agency and FDA to originally accept this pasteurized water equivalent system process. However, if any changes are made to the current UV light system or the current system is replaced, the UV light system would be required to be brought into compliance with the new requirements for UV light as cited in the 2009 PMO.

49. **PMO-Section 7, Item 15p(B); and Appendix H, Section IX**

When using ultraviolet (UV) light as an alternative for pasteurized water it must meet the requirements of Section IX-Accepted Process for the Creation of Pasteurized Equivalent Water, Appendix H-Pasteurization Equipment and Procedures and Other Equipment, of the PMO. Must the UV light process being utilized also comply with Item 15p(B)-Protection from Contamination requirements of the PMO that state that water samples are required to be tested daily for two (2) weeks following the approval of the initial installation, every six (6) months thereafter, and daily tests conducted for one (1) week following any repairs or alterations to the system?

No.

50. **PMO-Section 7, Item 16p**

A milk plant is proposing to install and operate the following system:

Whey HTST --- UF Membrane System --- Pasteurized Retentate Storage --- Condensed in an Evaporator and Dried

NOTE: Pasteurized Retentate Storage: This pasteurized retentate will not be shipped out of this milk plant.

Does this pasteurized retentate have to be re-pasteurized prior to being condensed in the evaporator?

No.

51. **PMO-Section 7, Items 16p(A), 16p(B) and 16p(C)**

For airspace, indicating and recording thermometers for which an M-b has been issued and the manufacturer's specifications submitted and reviewed cited a specified thermometer sensor, (i.e., a 1000 ohm sensor), if the sensor is changed to a 100 ohm sensor would this be acceptable under the issued M-b and the PMO?

No. A change in the resistance of the sensor or replacement of a dual probe with a single probe would change this equipment's compliance with the M-b that was issued and consequently it's compliance with the PMO. This modified unit would have to be resubmitted and reviewed before any acceptance of this modification would be made.

52. **PMO-Section 7, Item 16p(B)**

Section 7, Item 16p(B)-HTST Continuous-Flow Pasteurization, Administrative Procedures #2. b. (8), of the PMO requires that an HHST system, which has the FDD located downstream from the regenerator and/or cooler, must be thoroughly cleaned after a system diversion, including the divert line, if there is a cooler in the divert line that is not self-draining. Is a similar thorough cleaning also required if the FDD is not self-draining?

Yes.

53. **PMO-Section 7, Item 16p(B); and Appendix H, Section VI**

Is it acceptable to be able to remotely turn on and off a homogenizer, which is used as the timing pump on a computerized system for the public health controls of a pasteurization system, using a telephone from a location outside the milk plant, such as a distant city or country?

No.

54. **PMO-Section 7, Item 16p(E); and Appendix H, Section IV**

Newer models of electronic temperature recording devices used on batch pasteurizers can be configured to meet, or vary from, the requirements for batch pasteurizer temperature recording devices as specified in Section IV-Thermometer Specification, Temperature-Recording Devices for Batch Pasteurizers, Appendix H-Pasteurization Equipment and Procedures and

Other Equipment, of the PMO. For example, the rotation time for a circular chart can be configured for one (1) rotation in twelve (12) hours to seven (7) days or more.

a) If this can occur, must the electronic temperature recording device be sealed by the Regulatory Agency?

Yes. If it is not sealed, it would be considered a violation of Item 16p(E)-Pasteurization and Aseptic Processing Records, Equipment Test and Examinations, of the PMO.

b) Must the cap(s) on the sensor(s) that contain the RTD(s) for these electronic batch pasteurizer temperature recording devices be sealed if they provide access to and the ability to change the RTD?

Yes. If the sensor(s) is not sealed, they would be considered a violation of Item 16p(E)-Pasteurization and Aseptic Processing Records, Equipment Tests, and Examinations of the PMO.

55. **PMO-Section 7, Item 17p; and Appendix D, Section VII**

The following question relates to the requirements for intermediate open tower water pressure differential controls. What is the rationale for the addition of the differential pressure control requirements when the differential pressure control already existed between the intermediate cooling water loop and the product loop?

Item 17p-Cooling of Milk and Milk Products of the PMO prohibits the use of unsafe water to heat or cool milk or milk products with or without pressure controls. The purpose of the pressure controls between the unsafe open tower water and the water in the intermediate loop is to prevent the safe water in the intermediate loop from becoming contaminated with unsafe water from the open tower water.

56. **PMO-Section 7, Item 17p; and Appendix H, Section IV**

Item 17p-Cooling of Milk and Milk Products of the PMO requires an indicating thermometer on silos/tanks that are used to store pasteurized product. Is it acceptable to use a recording thermometer, which meets applicable requirements of Section IV-Thermometer Specifications, Appendix H-Pasteurization Equipment and Procedures and Other Equipment, of the PMO with an RTD and digital LED display, which indicates the temperature of the milk or milk product stored in the silo/tank, to be utilized as the indicating thermometer that is required on such pasteurized storage silos/tanks?

Yes. Thermometers with one (1) sensing probe and outputs to both a digital (indicating) display and a recording device would be acceptable.

57. **PMO-Section 7, Item 19p**

Does the capping requirement of "removal cannot be made without detection" as cited in Item 19p-Capping, Container Closure and Sealing and Dry Milk Product Storage of the PMO apply to multi-use and single service glass containers?

Yes.

58. **PMO-Appendix B, Section I**

A bulk milk hauler/sampler is utilizing a ladle for their sampling device, which is transported in the cab of the milk tank truck, and is being sanitized at each individual farm using sanitizer available on that farm, for the collection of an official milk sample at each farm. Is the storage of this ladle in an open plastic bucket an acceptable means of storing the ladle between uses?

No. When using a clean, plastic bucket as described above as the sampling device container, the ladle must be protected at all time during storage and transportation by the use of an appropriate clean lid/cover. If the ladle handle is longer than the depth of the plastic bucket than appropriate protection may be accomplished by using a required covered and clean plastic bucket and cutting a small hole the width of the handle in the lid for the handle to stick out of.

NOTE:

- *The sample dipper or other sampling devices, in this case a ladle, must be of sanitary design, approved by the State Regulatory Agency, clean and in good repair.*
- *The bulk milk hauler/sampler is expected to use an acceptable sanitizer, at the prescribe level, to sanitize the ladle at each farm prior to sample collection.*
- *The bulk milk hauler/sampler must have available an appropriate test kit for each of the sanitizers that will be used on the dairy farms for the collection of a milk sample.*
- *The ladle must be properly sanitized well onto the handle based on the depth that the ladle will be submerged in the milk for the collection of the official sample.*

59. **PMO-Appendix B, Section I; and Standard Methods for the Examination of Dairy Products (SMEDP)**

If a sample case contains multiple racks of samples does each rack require a temperature control (TC) or can one (1) TC cover all of the samples in the sample case?

If the multiple racks of samples indicate the dairy farms that were picked up on the milk tank truck load of milk that is being delivered, then one (1) TC collected at the first stop on the load and which is properly labeled would be sufficient. However, if the multiple racks indicate samples from more than one (1) milk tank truck load, than each rack(s) of samples from each individual milk tank truck load must have an appropriate and properly labeled TC for each individual milk tank truck load.

60. **PMO-Appendix B, Section I; and Appendix J, Section A**

Do single service sample containers (vials, whirl pak bags, etc.) used by bulk milk hauler/samplers have to come from an IMS listed single service manufacturer?

Not if they are considered a sterile sample container as defined in Chapter 3-Sampling Dairy and Related Products, *3.030-Equipment, 3.0333-Sample Containers, B. Single-service containers, 1 of the Standard Methods for the Examination of Dairy Products (SMEDP), 17th edition*.

Yes, if they are considered non-sterile sample containers.

Within Section I-Milk Sampling and Hauling Procedures, 7. Sampling Responsibilities, a., Appendix B-Milk Sampling, Hauling and Transportation, of the PMO it references the SMEDP. It states that all sample containers and single-service sampling tubes used for sampling shall comply with the requirements that are in the current edition of SMEDP.

Chapter 3-Sampling Dairy and Related Products, 3.030-Equipment, 3.0333-Sample Containers, B. Single-service containers, 1, of the SMEDP-17th Edition cites: Sterile; made of nontoxic food-grade plastic and 2. Non-sterile; made of nontoxic food-grade plastic---for raw milk and cream only--assuming the following conditions are met:

> *c. Government agencies have the authority to inspect and certify manufacturers to ensure the fabrication process and materials are acceptable for single-service containers.*

The footnotes to this Section cite the PMO and Form FDA 2399-Milk Sample Collector Evaluation Report-Dairy Plant Sampling-Raw and Pasteurized Milk and 2399a-Bulk Milk Hauler/Sampler Evaluation Report.

61. **PMO-Appendix B, Section IV**

Is a stainless steel #2b finish equivalent to a #4 finish for the interior milk contact surfaces of milk tank trucks?

Milk contact surfaces, including the inside of milk tank truck, that have not been polished but have been made from #2b cold rolled mill finish stainless steel and have been found to be at least as smooth as a 32 µin. (0.8 µm) roughness average (R_a) finish would be acceptable and are considered to be equivalent to a #4 polished finish if the sheets of #2b material have been inspected and selected to be free of imperfections such as pits, folds, and crevices.

3-A Sanitary Standard #05-15-Stainless Steel Automotive Milk and Milk Product Transportation Tanks for Bulk Delivery and/or Farm Pick Up requires a surface finish at least as smooth as a #4 ground finish on stainless steel sheets and be free of imperfections such as pits, folds, and crevices in the final fabricated form.

62. **PMO-Appendix B, Section IV**

Section IV-Milk Tank Truck Permitting and Inspection, Item 5. Wash and Sanitize Record, e., Appendix B-Milk Sampling, Hauling and Transportation, of the PMO states: "States will submit to the NCIMS Executive Secretary an updated list of all currently permitted non-IMS listed milk tank truck cleaning facilities . The list is to be submitted for publication on the NCIMS or other easily accessible web site." Does this wording require the State Regulatory Agency to submit an updated list of all currently permitted non-IMS listed milk tank truck cleaning facilities to the NCIMS Executive Secretary or is this considered a voluntary submission of this information?

An updated list of the currently permitted non-IMS listed milk tank truck cleaning facilities is required to be submitted by the State Regulatory Agency to the NCIMS Executive Secretary. This determination was made following a discussion with the author of Proposal 235 from the 2005 NCIMS Conference and his statement that the intent was for the submission to be mandatory. The State Regulatory Agencies readily have this information and with a single point to submit the information to this makes it workable for milk plants to access that information in a timely manor. States are also required to update this list when warranted.

NOTE: *If a State Regulatory Agency has not reported this information to the NCIMS Executive Secretary it is recommended that the State Regulatory Agency be made aware of this PMO requirement so that they can submit the required information to the NCIMS Executive Secretary. If after a period of time they have not reported this required information to the NCIMS Executive Secretary then it would be identified in their State Program Evaluation Report as a deficiency and a recommendation would be included in the report for the State to comply with this PMO required submission of a list of permitted non-IMS listed milk tank truck cleaning facilities to the NCIMS Executive Secretary.*

63. **PMO-Appendix H, Section I**

The following questions relate to Section 1-HTST Pasteurization, Pressure Relief Valves, Located within HTST Systems, 2-Downstream from the Holding Tube, Item c, Appendix H-Pasteurization Equipment and Procedures and Other Equipment, of the PMO.

a) When a pressure relief valve is located downstream from a HTST FDD, the pasteurized product must either rise twelve (12) inches above the highest raw product in the system and be open to the atmosphere at that point, before the entrance to the regenerator, as described in Item 2.a.; or after the exit of the regenerator and before the pressure relief valve, as described in item 2.b.; or the pressure relief valve must not be able to be forced open except with the aid of the liquid flowing through the system in any mode – "Product", "CIP", or "Inspect", as described in Item 2.c.

When applying Item 2.c., if this valve cannot be opened without the aid of the liquid flowing in the system, how are the valves pulsed for cleaning during "CIP"?

While the PMO does not specify what means a milk plant may use to cause the spring loaded pressure relief valve described in Item 2.c. to pulse during cleaning; many milk plants have chosen to use a spring-to-close pressure relief valve with air assist for this purpose. In this case, the air assist is set to hold the valve closed at a pressure greater than exerted by the flow of the liquid through the system. The spring alone, without the air assist, is designed to exert less than the pressure that is exerted by the liquid flowing through the system.

The public health concern is that the valve must be closed and not leaking during a shut down when liquid is not flowing through the system and the spring alone can close the valve.

During normal operation in "Product" mode the air assist is continuously on and holds the pressure relief valve closed unless there is a downstream blockage that causes the liquid pressure to rise above the preset air assist

air pressure. During "CIP", the air assist is turned on and off. Because the spring pressure, without the air assist, is less than the pressure exerted by the flowing CIP solution, the valve opens when the air assist is off. When the air assist is on, the valve again closes. This allows the milk plant to control the pulsing and cleaning of the valve during "CIP". For example, if the normal liquid pressure in a HTST system is thirty (30) pounds or greater then the spring selected could be one that can be forced open at twenty (20) pounds. When the air assist is periodically deactivated during "CIP", the valve will open, because the cleaning solution is flowing through the system at greater than the 20 pound spring pressure, but will close when the air assist is again activated.

b) Is it possible to raise the pressure in the HTST system sufficiently to open the pressure relief valve without using an air assist to open it?

Yes.

c) If so, how is the length of time the valve is open controlled and thus insuring the proper pulsing and cleaning of the valve? **NOTE:** If you raise the pressure high enough to open the pressure relief valve you increase the risk of blowing the press.

Simply raising and lowering the HTST system pressure in the "CIP" mode, such as by changing the air pressure to a system back pressure throttling valve that is often located at the end of the system, to open and close, a spring-to-close pressure relief valve, would meet the intent of the PMO but would be more difficult to control. With adequate safety precautions and operational controls, this method would also be acceptable.

d) Is the only way to satisfy the PMO and control the pulsing of the pressure relief valves during "CIP" to use an air assist to hold the valve closed during "CIP" and then deactivate the air assist to allow the pressure of the liquid flowing through the system to overcome the spring pressure and open the valve?

No. Any other means that will assure that the pressure relief valve cannot be opened without the assistance of flowing liquid, so it will automatically be closed when the system is shut down, whether in "Product", "CIP" or "Inspect" mode, would also be acceptable. (Refer to the answer for question b. for an example.)

64. **PMO-Appendix H, Section I**

Within Section 1-HTST Pasteurization, Pressure Relief Valves, Located within HTST Systems, 1. Between the Timing Pump and the Beginning of the Holding Tube, **OPTION I**, Appendix H-Pasteurization Equipment and Procedures and Other Equipment, of the PMO must the leakage from this

pressure relief valve be readily visible, such as the vent being open to the floor or provided with an appropriately installed sight glass?

*No. However, it would be required if **OPTION II** is being utilized.*

65. **PMO-Appendix H, Section IV**

What does the term “salt fog” mean as cited within Section IV- Thermometer Specifications, Temperature-Recording Devices for Batch Pasteurizers (and in other locations within Section IV), Appendix H-Pasteurization Equipment and Procedures and Other Equipment, of the PMO?

1. Digital:

“d. The effect of exposure to specific environmental conditions shall be documented. The device must be tested to determine the effects of low and high temperatures, thermal shock, humidity, physical shock and **salt fog**.”

Environmental testing conducted during the design stages of electronic devices is used to predict how well the device will withstand various environmental conditions to which the device could be exposed.

Salt Fog testing, also known as salt spray testing, is normally conducted in a salt fog chamber to simulate extended environmental exposure. Testing is applied to the entire device and is used to test the corrosion resistance of the surfaces of the device such as the probe, cabinet and the protection that the sealed coated cabinet will provide to the electronic circuitry inside the cabinet.

66. **PMO-Appendix I, Section II (Test 2)**

a) Test #2-Recording Thermometers - Temperature Accuracy, "Application", Section II-Test Procedures, Appendix H-Pasteurization Equipment and Controls –Tests, of the PMO states that this Test applies to all mercury-actuated recording and recorder-controller thermometer controllers used to record milk or milk product temperatures during pasteurization or aseptic processing. What types of recording and recorder-controller thermometer controllers does the term "mercury-actuated" apply to?

The term "mercury actuated" type thermometer was historically used to categorize all non-digital or older technology reference thermometers. "Mercury actuated" type recording thermometer represent the older and in some cases obsolete technology for recording thermometers. They have been called capillary type, Bourdon tube based or filled bulb type of which each term describes vapor filled or mercury filled technology, which was commonly used in most pre-1990 recording thermometers.

Below are some examples that describe the following temperature recorder and recorder-controller thermal systems:

VAT

- *Taylor 352R, which uses a Bourdon coil device that contains an ether derivative.*
- *Partlow RFT-J703 (M-b-177) uses a mercury filled thermal sensor.*

HTST

- *Taylor STLR 1400J with X210 Transmitter (M-b-252) can be equipped with filled thermal systems that contain Mercury (SAMA Class V), Organic Liquid (Class IB or IA), Vapor, or Gas (Class III).*
- *Partlow RFH-J673 (M-b-166) and RFH-J755 (M-b-224) use a mercury filled thermal sensor.*
- *Foxboro 120 Series STLR (M-b-249) uses an SAMA Class IIIB gas compression system.*

b) Is Test #2 required to be conducted on a quarterly basis for all types of "mercury-actuated" (i.e., Bourdon tube, mercury, organic liquid, vapor, gas actuated, etc.) recorder and recorder-controller thermal systems?

Yes.

67. **PMO-Appendix I, Section II (Test 5)**

With a pasteurization system utilizing computer controls for the public health controls, would the manual divert located in a stand alone cabinet/box or the required time-delay relays for the flush delay, “Product”, “Inspect” or “CIP” modes be required to be sealed by the Regulatory Agency similar to a traditional pasteurization systems as cited in Section II-Test Procedures, Test 5-FDD-Proper Assembly and Function, Appendix I-Pasteurization Equipment and Controls – Tests, of the PMO?

The stand alone cabinet/box would be required to be sealed by the Regulatory Agency only if any of the public health controls or timers, computer or hard wired, could be compromised from inside the cabinet/box. In addition, any communications ports to the cabinet/box that could be used to alter computer programs or ladder logic that would cause an alteration of the public health controls or timers must be properly disabled or sealed by the Regulatory Agency.

68. **PMO-Appendix I, Section II (Test 9)**

Section II-Test Procedures, Test 9-Regenerator Pressure Controls, Appendix I-Pasteurization Equipment and Controls – Tests, of the PMO requires verifying that the booster pump is properly interwired with the following:

- Pressure Differential Controller–Test 9.2.2
- Flow-Diversion Device (FDD)–Test 9.3.1
- Timing Pump-Test 9.3.2.

In magnetic flow meter based timing systems (MFMBTS), the flow through the system is developed by a combination of flow promoting devices, including booster and stuffer pumps, separators and clarifiers, homogenizers and positive displacement pumps. Is Test 9.3.2.-Booster Pumps–Interwired with the Timing Pump, which verifies the operation of the booster pump when the power to the flow meter is interrupted, required to be performed?

No. The high and low flow alarms in conjunction with other required public health safeguards eliminate the need for this Test to be conducted.

69. **PMO-Appendix J, Section A**

The dispensing nozzle on aerosol containers containing Grade "A" milk or milk products are covered by a plastic cover/cap. Is this plastic cover/cap required to come from an IMS listed source?

No. The closure is considered to be the nozzle assembly. This plastic cover/cap protects the nozzle assembly closure but is not considered to be a component part of the closure.

70. **PMO-Appendix J, Section A**

Does the straw that is attached to a carton of milk or milk product or the spoon that is attached to a container of yogurt or cottage cheese required to come from an IMS Listed source?

No. Neither the straw nor the spoon is considered a container or a closure, nor are they considered a component part of a container or closure, and; therefore, would be outside the scope of Appendix J of the PMO.

71. **PMO-Appendix J, Section D, Item 13; and Appendix H, Section II**

a) When air under pressure is directed at resin, regrind, colorants and similar materials or at container or closure product-contact surfaces, does the PMO require that the piping (tubing), fittings and connections, which are

located downstream from the final filter and the point of application, be constructed of plastic, rubber, rubber-like, stainless steel or other non-toxic, relatively nonabsorbent material?

Yes.

b) Would brass fittings and connections be considered to comply with the answer provided in a) above?

Yes, if they are not corroded or in poor condition.

72. **PROCEDURES GOVERNING THE COOPERATIVE STATE-PUBLIC HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION PROGRAM OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS (PROCEDURES)-Section IV**

a) What is the shipping State's obligation under the Procedures if a single farm BTU's dairy producer goes out of business and their permit is canceled (revoked)?

Section IV.-Oversight and Responsibilities, B. State Responsibilities, 1. d of the Procedures requires that when a certified interstate milk shipper's supply, raw or pasteurized, changes status because of degrading, ***permit revocation****,* ***significant change in number of producers****, or change in the Sanitation Compliance or Enforcement Rating to less than ninety percent (90%), the shipping State shall immediately notify all known receiving States and the appropriate PHS/FDA Regional Office.*

A single farm BTU is very unique in that it is IMS listed based on one (1) specific producer and the associated valid State issued permit. If that specific producer and associated permit is ***canceled (revoked)*** *because they have gone out of business or for any other reason, then that BTU is no longer valid and the shipping State is required to immediately report this information to all known receiving States and the appropriate FDA Regional Office.*

With a single farm BTU and the producer goes out of business this would also be considered a ***significant change in the number of producers*** *and would require the shipping State to immediately notify all known receiving States and the appropriate FDA Regional Office.*

b) What is FDA's obligation under the Procedures when they are notified of this action?

FDA's Regional Office will forward that notification to CFSAN, where that BTU's listing will be immediately withdrawn from the IMS List.

73. **MMSR-Section C**

Within Section C-Rating Methods for Milk Plants, Receiving Stations and Transfer Stations, 2-Collection of Data, b-Recording of Laboratory and Other Test Data, 2.), of the MMSR it requires that a debit shall be given when less than the required number of samples has been examined during the preceding six (6) months of a rating. Does this statement mean that if a milk plant is withdrawn from the IMS List due to the improper number of samples being collected and examined, that the Rating Agency can IMS List the milk plant with just one (1) new sample; or is it a requirement to have four (4) samples in the preceding six (6) months of the new rating; or does it mean one (1) sample in the month of the new rating and only three (3) in the previous six (6) months; or what?

When a milk plant is withdrawn from the IMS List for sampling frequency deficiencies it does not get to start over with a clean sampling frequency slate. The State Rating Agency may conduct a new rating and re-list the milk plant with a Sanitation Compliance Rating of ninety (90) or greater, which would include that the sampling frequency requirement of the PMO has been reestablished for the preceding six (6) months of the new rating date. This could be as short as a few days because only one (1) sample was required to be collected and examined to meet the sampling frequency or as long as three (3) months because four (4) samples were required to be collected and examined.

NOTE: *For rating purposes during any consecutive six (6) month period, at least four (4) samples shall be collected and examined, in at least four (4) separate months, except when three (3) months show a month containing two (2) samples separated by at least twenty (20) days is permitted when evaluating the sample frequency requirements of the PMO. With this scenario, Rating Officers will not be looking for accelerated sampling as would be the case in a situation where a permit is suspended because three (3) of the last five (5) samples examined exceed the PMO standards, i.e., bacterial counts, coliform determinations or cooling temperatures. Also, for State Rating and check rating purposes, the preceding six (6) months is considered to be the elapsed period of the month in which the State Rating or check rating is made and the preceding six (6) months. Milk plants which have had a permit for less than six (6) months at the time of the State Rating or which do not operate on a year round basis and for which the Regulatory Agency has not yet examined the required number of samples shall not be debited. Provided, that the last sample result is within the limit(s).*

This question may best be addressed and explained by using some examples.

Example #1: *A Rating Officer conducts a State Rating on a milk plant on August 13, 2009. The rating resulted in a withdrawal of the milk plant from the IMS List. One of the reasons for the withdrawal was that an insufficient number of the milk plant's pasteurized milk and milk products were collected and examined, which contributed to the milk plant's Sanitation Compliance Rating of less than ninety (90) resulting in the withdrawal.*

The last State Rating was conducted on October 10, 2007. A review of the Regulatory Agency's records indicated that the milk plant's milk and milk products were collected and examined (bacteria, coliform, drugs, phosphatase and cooling temperature) on the following dates:

- *Monthly samples were taken from October 2007 through January 2009.*

- *Following is the elapsed period of the month in which the rating was made and the preceding six (6) months to be used by a Rating Officer when determining if sanitation compliance points (twenty (20) total, which includes ten (10)-Coliform, five (5)-Bacterial and five (5)-Cooling, depending on the specific tests required for the specific milk or milk product) are going to be taken off under Sanitation Compliance for the specific product(s). The preceding six (6) month time frame of the State Rating to be used in determining the sampling frequency requirements of the PMO is* ***August 12, 2009 to February 1, 2009****.*

  February (No Samples)
  March (No Samples)
  April 10, 2009
  May (No Samples)
  June 14, 2009
  July 17, 2009
  August 13, 2009-State Rating Date (No Samples Collected to Date)

- *Within this period of time they must have four (4) samples collected and examined in at least four (4) separate months, except one (1) month may have samples separated by at least twenty (20) days, to obtain credit and not be debited under the Sanitation Compliance Rating. Remember that this preceding six (6) months definition only applies to the Sanitation Compliance Rating, and violations are prorated by specific milk or milk product's daily processing volume.*

  NOTE: *Any consecutive six (6) month period must meet the sampling frequency requirements of the PMO or they are debited under FORM FDA 2359j-Report of the Milk Sanitation Rating, Section B-Report of Enforcement Methods, Milk Plant-Part II-Item 7-Samples of each*

plant's milk and milk products collected at required frequency and all necessary laboratory examinations made for that specific milk or milk product(s).

- *With this example, the milk plant would lose the corresponding points on the Sanitation Compliance Rating for the required test(s)/milk or milk product(s), based on the daily processing volume of that milk or milk product(s), and also would lose points on the Enforcement Rating for the specific milk or milk product(s) not meeting the sampling frequency requirements of the PMO. If this would cause the Sanitation Compliance Rating to fall below ninety (90), the shipper would be immediately withdrawn from the IMS List.*

- *Following the IMS Listing withdrawal, if a sample is collected and examined of the specific milk or milk product(s) in either the remaining days of August or in September 2009, than a State Rating could be conducted after the sample collection date without the Sanitation Compliance Rating being debited for not meeting the milk and milk product(s) sampling frequency requirement of the PMO for the preceding six (6) months of the rating.*

Example #2: *The same scenario as identified in Example #1 above; however, the following samples were collected and examined by the Regulatory Agency. The State Rating was conducted August 13, 2009, which resulted in a withdrawal of the shipper from the IMS List. The previous State Rating was conducted October 10, 2007.*

- *Monthly samples were taken from October 2007 through January 2009.*

- *The preceding six (6) month time frame of the rating to be used in determining the sampling frequency requirements of the PMO is **August 12, 2009 to February 1, 2009**.*

  February (No Samples)
  March 10, 2009
  April (No Samples)
  May (No Samples)
  June 14, 2009
  July 17, 2009
  August 8, 2009
  August 13, 2009-State Rating Date

- *In this example, the milk plant would not be debited under the Sanitation Compliance Rating because the milk plant has four (4) samples in the preceding six (6) months of the State Rating; however,*

they would be debited under the Enforcement Rating for the specific product(s) affected because of missing the milk and milk product sampling frequency requirement of the PMO for the time period of February 1, 2009 to July 31, 2009.

74. **MMSR-Section D**

May an IMS Listed milk plant receive milk from a BTU that is currently not shown on the IMS Listing? The State Rating Officer contacted the State Rating Agency and they stated that a State Rating had been recently conducted with both the Sanitation Compliance and Enforcement Ratings being ninety percent (90%) or higher.

Yes, as long as the shipper has signed and submitted a Permission to Publish for this most recent State Rating to the State Rating Agency.

In situations where a BTU or other shipper is not on the current IMS List it is strongly recommended that the State Rating Officer contact the State Rating Agency to find out if a new State Rating had been recently conducted and that a signed Permission to Publish has been received by the State Rating Agency for this new State Rating before they take any action to withdraw a listed shipper from the IMS List for receiving milk or milk products from an unlisted source.

Also, hopefully, the State Rating Agency had not allowed the previous State Rating to expire before they conducted their next State Rating as this would constitute a milk plant receiving milk from an unlisted source during this time frame between the two (2) State Ratings.

75. **MMSR-Appendix A**

Appendix A-Guideline for Computing Enforcement Ratings, Part II-Milk Plants, Item 5-Pasteurization equipment tested at required frequency, c, of the MMSR requires that test results be entered on an appropriate ledger form, a computer or other information retrieval system. What is considered an appropriate ledger form and what information is required to be included on the ledger, computer or other information retrieval system to be acceptable?

Equipment test results are required to be recorded on a ledger form, a computer or other information retrieval system. Separate ledger forms, computer print-outs or other retrieval system reporting forms are required for each milk plant and each pasteurization system within that milk plant. The information recorded on the individual ledgers, computer or other retrieval systems should include:

1. *The plant identification (name/address or plant code);*
2. *Identification of each individual pasteurization system (i.e., vat #1, HTST #2, HHST, ultra-pasteurization (UP), or aseptic processing/packaging system);*
3. *Identification of the specific Tests as they relate to FORM FDA 2359b-Milk Plant Equipment Test Report or an equivalent form;*
4. *Date that each individual equipment testing was conducted;*
5. *A remarks column to record such information as the reason for the testing, (i.e., broken seal, system modifications, new equipment installed, etc., any corrective action take; or other applicable comments, etc.);*
6. *An "X", "√", "OK", "yes" are all acceptable responses to indicate the individual Tests that were completed for that specific date.*

NOTE: *The* ***actual*** *Test results may be recorded on the ledger, computer or other retrieval system but are not required and the lack of the* ***actual*** *Test results on the ledger, computer or other retrieval system will not be considered a violation of this Item and will not be debited on State Ratings and check ratings. However, during State Ratings and check ratings, individual FORM FDA 2359b-Milk Plant Equipment Test Reports or equivalent forms will be reviewed to assure that each Test was properly completed; that the Test results are within the PMO requirements; and that the appropriate required corrective action was taken if a Test result was not in compliance with the criteria for that specific Test.*